



PTO/SB/08a (08-03)

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Substitute for form 1449a/PTO

# FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 1 of 2

## Complete if Known

Application Number	10723,933
Filing Date	November 26, 2003
First Named Inventor	James, Kenneth D. Ph.D.
Art Unit	1642
Examiner Name	Nichols, Christopher J.
Attorney Docket Number	014811-205.108

## U.S. PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	D1	US- 4,044,196	08/23/1977	Hüber et al.	
	D2	US- 4,179,337	12/18/1979	Davis et al.	
	D3	US- 4,526,938	07/02/1985	Churchill et al.	
	D4	US- 5,013,556	05/07/1991	Woodie et al.	
	D5	US- 5,108,568	04/28/1992	Van Alstine	
	D6	US- 5,773,581	06/30/1998	Camble et al.	
	D7	US- 6,506,730	01/14/2003	Lee et al.	
	D8	US- 2003/0060906 A1	03/27/2003	Ekwuribe et al.	
	D9	US- 2003/0069170 A1	04/10/2003	Soltero et al.	
	D10	US- 2003/0153488 A1	08/14/2003	May et al.	
		US-			
		US-			
		US-			
		US-			
		US-			

## FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	D11	EP 0 092 918	11/02/1983	Imperial Chemical Industries PLC		
	D12	EP 0 354 855	02/14/1990	Terumo Kabushiki Kaisha		
	D13	EP 0 381 070	08/08/1990	Farni Hispania S.A.		
	D14	WO 00/43034	07/27/2000	Eli Lilly and Company		
	D15	WO 02/098232 A1	12/12/2002	Nobex Corporation		
	D16	WO 03/022996 A2	03/20/2003	Nobex Corporation		
	D17	WO 03/022208 A2	03/20/2003	Nobex Corporation		
	D18	WO 03/022210 A2	03/20/2003	Nobex Corporation		

Examiner Signature	/Andrew D. Kosar/	Date Considered	02/02/2009
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO  <b>FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/723,933	
			Filing Date	November 26, 2003	
			First Named Inventor	James, Kenneth D. Ph.D.	
			Art Unit	1642	
			Examiner Name	Nichols, Christopher J.	
Sheet	2	of	2	Attorney Docket Number	014811-205.108

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		† <sup>2</sup>
	D19	KANG CHOON LEE, et al.; Isolation, Characterization, and Stability of Positional Isomers of Mono-PEGylated Salmon Calcitonins; Pharmaceutical Research; 1999; Vol. 16, No. 6, pp. 813-818; Plenum Publishing Corporation		
	D20	HAESHIN LEE, et al.; Preparation and Characterization of Mono-PEGylated Epidermal Growth Factor: Evaluation of <i>in Vitro</i> Biologic Activity; Pharmaceutical Research; 2002; Vol. 19, No. 6, pp. 845-851; Plenum Publishing Corporation		
	D21	ANDREA LUCKE, et al.; Biodegradable poly(D,L-lactic acid)-poly(ethylene glycol)-monomethyl ether diblock copolymers: structures and surface properties relevant to their use as biomaterials; Biomaterials; 2000; 21, pp. 2361-2370; Elsevier Science Ltd.		
	D22	JONG-HOON LEE, et al.; Polymeric nanoparticle composed of fatty acids and poly(ethylene glycol) as a drug carrier; International Journal of Pharmaceutics; 2003; 251, pp. 23-32; Elsevier Science B.V.		
	D23	WEI WANG, et al.; AlbuBNP, a Recombinant B-Type Natriuretic Peptide and Human Serum Albumin Fusion Hormone, as a Long-Term Therapy of Congestive Heart Failure; Pharmaceutical Research; 2004; Vol. 21, No. 11, pp. 2105-2111; Springer Science+Business Media, Inc.		
	D24	SAMUEL ZALIPSKY; Synthesis of an End-Group Functionalized Polyethylene Glycol-Lipid Conjugate for Preparation of Polymer-Grafted Liposomes; Bioconjugate Chemistry; 1993; 4, pp. 296-299; American Chemical Society		
	D25	MUNEAKI HASHIMOTO, et al.; Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities; Pharmaceutical Research; 1989; Vol. 6, No. 2, pp. 171-176; Plenum Publishing Corporation		
	D26	MARY L. NUCCI, et al.; The therapeutic value of poly(ethylene glycol)-modified proteins; Advanced Drug Delivery Reviews; 1991; 6, pp. 133-151; Elsevier		
	D27	MURRAY SAFFRAN, et al.; A New Approach to the Oral Administration of Insulin and Other Peptide Drugs; Science; 1986; Vol. 233, pp. 1081-1084		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.

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†Applicant's unique citation designation number (optional). †Applicant is to place a check mark here if English language Translation is attached.

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